UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/074,472	05/07/98	RICHTER M	337462000600

HM22/1206

GLADYS H MONROY
MORRISON & FOERSTER
755 PAGE MILL ROAD
PALO ALTO CA 94304-1018

EXAMINER	
CHAKRABARTI,A	
ART UNIT	**PAPER NUMBER**
1655	14

DATE MAILED: 12/06/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applic(s)
09/074,472	Richter et al
Examiner	**Group Art Unit**
Arun Chakrabarti	1655

☒ Responsive to communication(s) filed on *Nov 15, 1999*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-27* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-27* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Sequence Rules

The Sequence Rules amendment is a bona fide attempt to comply with the Sequence Rules, but a new CRF is required for the reason(s) set forth on the attached Raw Sequence Listing Error Report. A new Notice to Comply with Sequence Rules is also attached.

Miscellaneous

This action will not be made final due to the new rejections contained herein, which were not necessitated by amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 2, 4, 9, 19-21, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Chmura et al. (Journal of Biolumin Chemilumin (1994), Vol. 9, pages 1-6).

Chmura et al. teaches a method for detecting an analyte in a sample composition (abstract) comprising the steps of:

(a) preparing an assay mixture comprising: said sample composition; a reagent having an ECL label (which reagent is citrate methanol, which has weak luminescence, see page 2, column 2); and a reagent having an ECL quenching moiety (which reagents are those of table I, particularly reagents such as alpha-tocopherol which have benzene rings, see page 3, table I), said

ECL quenching moiety comprising at least one benzene moiety (Materials and Methods Section and Table 1);

(b) determining any difference between the ECL emissions of: (I) the assay mixture prepared in step (a); and, (ii) an assay mixture comprising: said reagent having an ECL label; said reagent having an ECL quenching moiety; and a known amount of said analyte (which analyte is anthracene, which is quantitatively related in intensity to ECL and quantitatively reduced by quenching agents of Table I, see page 3, figure 3 and table I); and, c) correlating any difference determined in step (b) with the amount of analyte in said sample (Materials and Methods Section, Table 1 and Figures 3, 4 and 5).

Chmura et al. teaches a method wherein said ECL quenching moiety comprises at least one moiety selected from the group consisting of phenol moieties, quinone moieties, benzene carboxylic acid moieties, and benzene carboxylate moieties (Table I).

Chmura et al. teaches a method wherein said ECL label comprises a polyaromatic hydrocarbon (Table I).

Chmura et al. teaches a method wherein known amount of analyte is zero (Figure 5).

Chmura et al. teaches a method wherein said reagent having an ECL label and said reagent having an ECL quenching moiety are either same or different reagent (Table 1).

3. Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Sigma Chemical Company (Catalog 1995).

Sigma catalog expressly teaches the reagents containing benzene moiety (pages 151 and 1820) including phenol (page 789) and benzene carboxylic acids (Page 151).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-6, 9, 19-21 and 24-27 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Chmura et al. (Journal of Biolumin Chemilumin (1994), Vol. 9, pages 1-6,) in view of Papalambros et al. (Journal of Photochemistry (1987), Vol. 39, pages 85-96).

Chmura et al teaches the methods and reagent claims of 1, 2, 4, 9, 19-21 and 24-27 as described above.

Chmura et al. does not teach the method wherein the quenching moiety comprises at least one phenol moiety, at least one benzene carboxylic acid moiety or at least one benzene carboxylate moieties .

Papalambros et al. teaches the method wherein the quenching moiety comprises at least one phenol moiety, at least one benzene carboxylic acid moiety or at least one benzene carboxylate moieties (Page 89, lines 32-37).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to include the group of chemicals containing substituted benzene rings of Papalambros et al. in the method of Chmura et al., since Papalambros et al. states "Substituted benzaldehydes, benzoic acids, esters of benzoic acids and benzene have similar ionization potentials for the same substituent. It follows, therefore, that electron transfer occurs from the

substituted benzene ring, irrespectively of the functional group present (carbonyl etc.) The quenching constants of the three products above will, therefore, be expected to be similar depending only on the substituent (Tables 1, 2 and 3 and Page 89, lines 32-37)." An ordinary practitioner would have been motivated to combine and compare the electrochemiluminescence quenching chemicals containing diferentially substituted benzene ring into the method of Chmura et al. in order to achieve the express advantages noted by Papalambros et al. of electrochemiluminescence quenching chemicals in which electron transfer occurs from the substituted benzene ring, irrespectively of the functional group present.

6. Claims 1, 2, 4, 7-9, 19-21, 24 and 25 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Chmura et al. (Journal of Biolumin Chemilumin (1994), Vol. 9, pages 1-6,) in view of Gudibande et al. (PCT International Publication Number WO 93/12256) (June 24, 1993).

Chmura et al. teaches the methods and reagent claims of 1, 2, 4, 9, 19-21 and 24-27 as described above.

Chmura et al. does not teach the method wherein said ECL label comprises Ruthenium or Osmium.

Gudibande et al. teaches the method wherein said ECL label comprises Ruthenium or Osmium (page 56, Claim 4, line 30).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to include ECL label comprising Ruthenium or Osmium of Gudibande et al. in the method of Chmura et al., since Gudibande et al. states "Electrochemiluminescent (ECL) assaying techniques are an improvement over other assay techniques. They provide a sensitive and

precise measurement of the presence and concentration of an analyte of interest. (Page 2, lines 23-27)." An ordinary practitioner would have been motivated to combine and compare the ECL label comprising Ruthenium or Osmium into the method of Chmura et al. in order to achieve the express advantages noted by Gudibande et al. of ECL assay techniques which can provide sensitive and precise measurement of the presence and concentration of an analyte of interest.

7. Claims 1, 2, 4 and 9-27 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Chmura et al. (Journal of Biolumin Chemilumin (1994), Vol. 9, pages 1-6,) in view of IGEN catalog (1996).

Chmura et al. expressly teaches the method claims and assay reagents of 1, 2, 4, 9, 19-21,24 and 25 as described above in detail.

Chmura et al. does not teach the method wherein said analyte comprises an oligonucleotide (DNA or RNA), polypeptide, antibody, antigen, an enzyme, an enzyme substrate, polysaccharide. Chmura et al. does not teach the method comprising the step of conducting a chemical reaction on a substrate present in an initial sample composition to produce said analyte in said sample composition either in step (a) or prior to step (a) before the determination of step (b).

IGEN catalog teaches the method wherein said analyte comprises an oligonucleotide (DNA or RNA), polypeptide, antibody, antigen, an enzyme, an enzyme substrate, polysaccharide. Chmura et al. does not teach the method comprising the step of conducting a chemical reaction on a substrate present in an initial sample composition to produce said analyte in said sample

composition either in step (a) or prior to step (a) before the determination of step (b) (See attached IGEN catalog).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to include any analyte detection including oligonucleotide (DNA or RNA), polypeptide, antibody, antigen, an enzyme, an enzyme substrate, polysaccharide of IGEN in the method of Chmura et al., since IGEN catalog provides motivation, "This study demonstrates that the detection of JC virus by electrochemiluminescence with the ORIGEN Analyzer was as sensitive as the standard isotopic procedure. Additionally, the ORIGEN Detection System provides objective, quantitative results read by a calibrated instrument increasing the precision of results over time. In addition, electrochemiluminescence offers a number of advantages over the standard detection procedure: 1) Non-radioactive, long lasting detection probes, 2) Savings of one to two days in obtaining results, and 3) Efficiency; requiring less material and manipulations to execute. In summary, quantitation of nucleic acid hybridization is highly simplified using the ORIGEN Detection System. In this case, coupling of the ORIGEN TAG label to oligonucleotides allows them to be used as specific hybridization and detection probes. The assay described above demonstrates the flexibility and speed with which the ORIGEN System can be applied for accurate quantitation of DNA hybridization assays (See Conclusion Section) ." An ordinary practitioner would have been motivated to combine and compare any analyte detection including oligonucleotide (DNA or RNA), polypeptide, antibody, antigen, an enzyme, an enzyme substrate, polysaccharide of IGEN into the method of Chmura et al. in order to achieve the express advantages noted by IGEN of ECL assay techniques which can provide 1)

Non-radioactive, long lasting detection probes, 2) Savings of one to two days in obtaining results, and 3) Efficiency; requiring less material and manipulations to execute.

8. Claims 1, 2, 4, 9, 19-21 and 24-27 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Chmura et al. (Journal of Biolumin Chemilumin (1994), Vol. 9, pages 1-6,) in view of Stratagene Catalog (1988, Page 39).

Chmura et al. expressly teaches the method claims and assay reagents of 1, 2, 4, 9, 19-21,24 and 25 as described above in detail.

Chmura et al. does not teach the motivation to combine all the reagents for detecting an analyte in a sample in the form of a kit.

Stratagene catalog teaches a motivation to combine reagents into kit format (page 39).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine a suitable container, ECL label and ECL quenching moiety of Chmura et al. into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small

number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control". (page 39, column 1).

Response to Arguments

1. Applicant's arguments filed November 15, 1999, have been fully considered but they are not persuasive.

The rejection under 35 U.S.C. 112, second paragraph was withdrawn in view of the amendment.

The rejection under 35 U.S.C. 102 and 103 using Weber, who taught hydrazine, a non-benzene ring quencher, is withdrawn.

As noted above, new rejections, not necessitated by amendment were made, and therefore this action is non-final.

With regard to the arguments on claims 24, in which no new reference is utilized, Applicant argues that there is no teaching in Sigma catalog which meets the claim requirement that the ECL reagent be the quenching moiety of claim 1. This argument is not persuasive, because any product which functions to quench an ECL reaction meets the structural requirements of claims 24. The specific intended uses contemplated by claim 1 are not relevant since they impose no structural change to the quencher other than to clearly require that the quencher have a benzene ring, which phenol and many other compounds found in the Sigma

catalog contain. As MPEP 2111.02 notes "Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim." Here, the phenol of the Sigma Catalog structurally meets the claim requirements.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JEFFREY FREDMAN
PRIMARY EXAMINER

Arun Chakrabarti,

Patent Examiner,

December 3, 1999